

# *US HPV Challenge and Beyond*

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Richard A. Denison, Ph.D.  
Senior Scientist  
Health Program



**ENVIRONMENTAL DEFENSE**

finding the ways that work

# Toxic Substances Control Act *Theory ...*

*TSCA Data Availability Policy (1976):*

“It is the policy of the United States that ... ***adequate data*** should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the ***responsibility of those who manufacture [such] chemicals.***”

## .... *and Practice*

National Academy of Sciences, *Toxicity Testing* (1984)

– 78% of high-volume chemicals lacked even “minimal toxicity information”

• Environmental Defense, *Toxic Ignorance* (1997)

– 71% of HPV sample: basic SIDS mammalian tox dataset not publicly available

• US EPA (1998)

– 93% of ~3000 HPV chemicals lacked publicly available SIDS data set (all elements)

– 43% had *no* publicly available SIDS data

• Chemical Manufacturers Association (1998)

– 91% of HPV chemicals lacked publicly available SIDS data set (all elements)

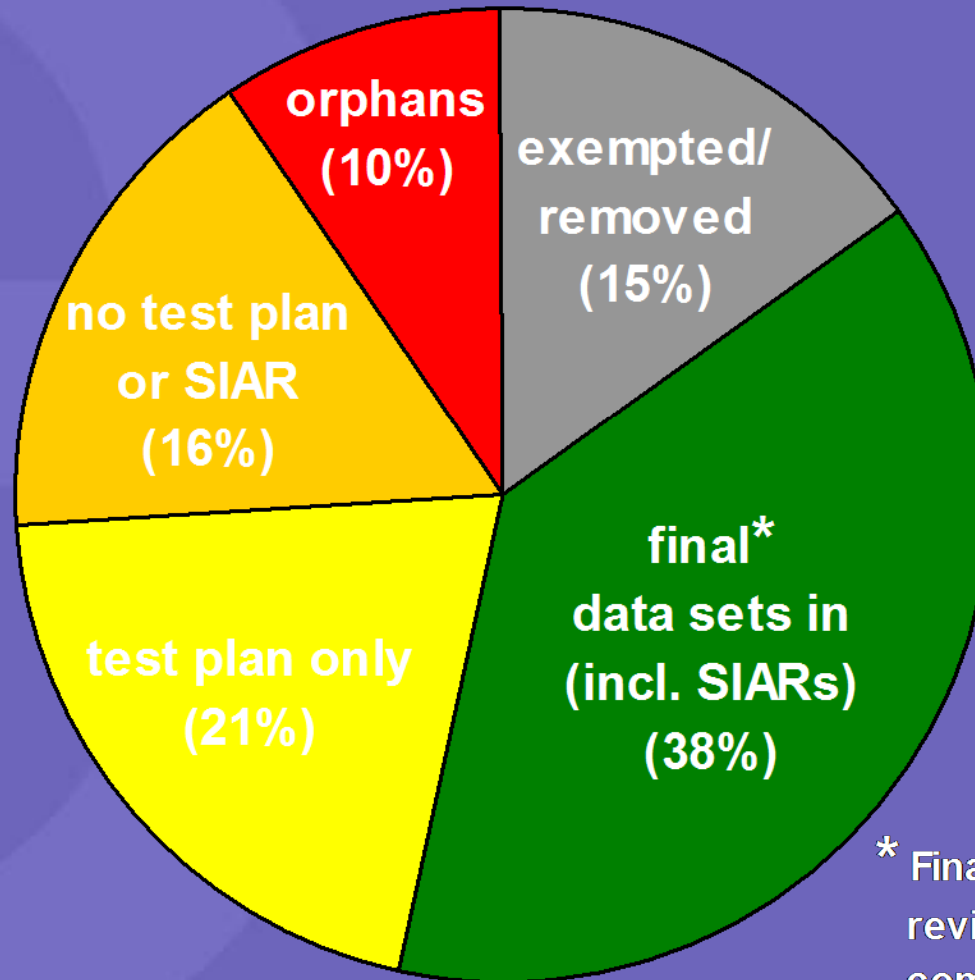
## *HPV Challenge Program Framework*

- Manufacturers to voluntarily “sponsor” HPV chemicals: identify, fill SIDS gaps
- Two routes deemed acceptable by EPA:
  - Through US program directly
  - Through parallel ICCA / OECD SIDS Program
- Work was to be completed by 2004, data made public by end of 2005

## *Status of the HPV Challenge Program*

- Sponsorship commitments:
  - made by ~400 companies and consortia
  - covering 2,274 chemicals
- 2,782 chemicals on original list (1990 HPVs)
  - 1,901 are sponsored (+ 373 *not* on list)
    - 1,167 directly under US program
    - 734 through ICCA/OECD program

Status of the 2,782 HPV Challenge  
Core List Chemicals as of December 2006



\* Final US datasets not yet reviewed for quality or completeness



## *Still to come?*

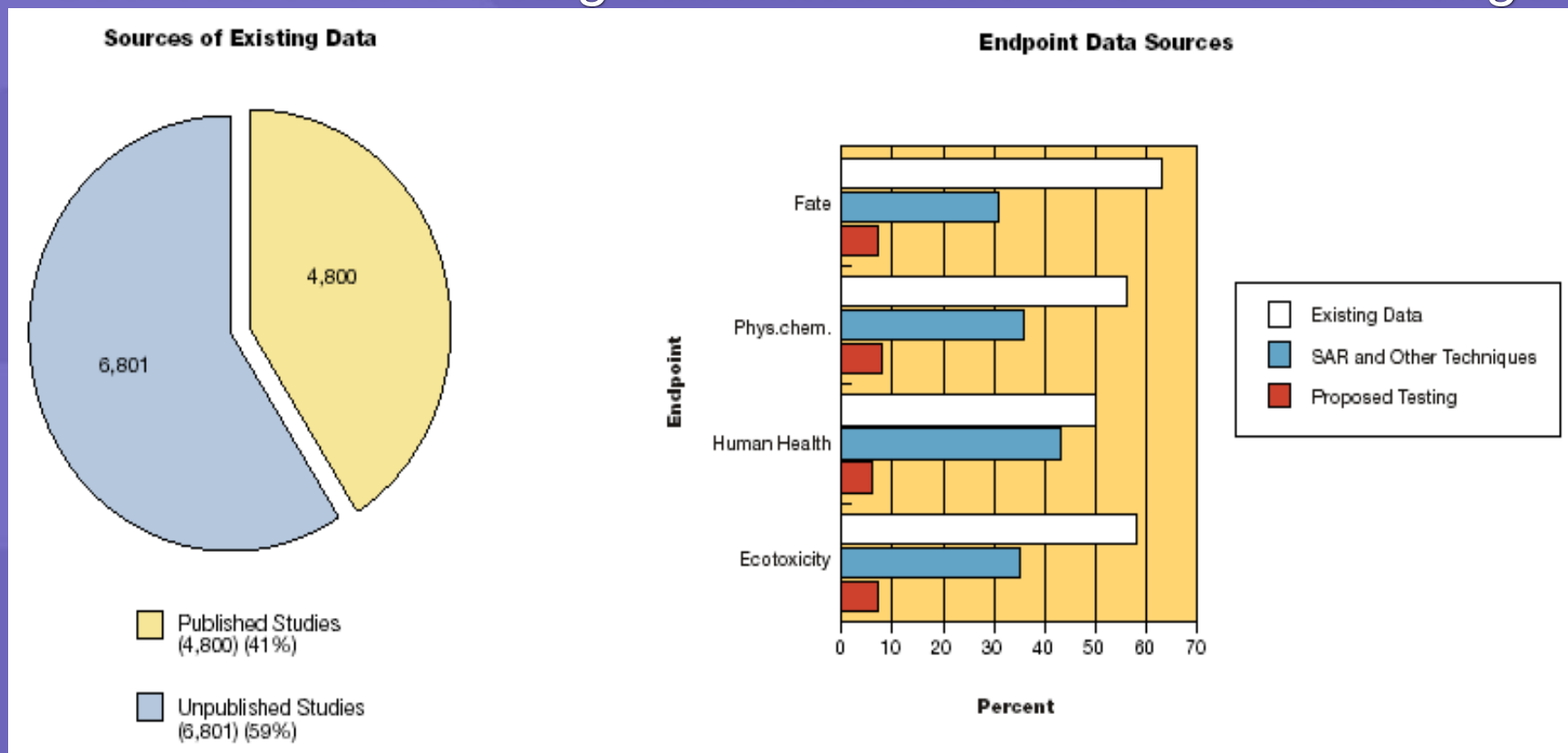
- 575 chemicals still lack final datasets
- 460 ICCA / OECD chems on much slower track
  - Includes consensus hazard assessment, only 50-100 chems/yr
- 265 “orphan” HPV chemicals = no sponsor
  - EPA to try to develop test rules for most of these, must show high exposure or potential risk and lack of data to compel testing
  - Test rule for 1<sup>st</sup> 17 HPVs took 5+ years

## *Still to come?*

- 574 “emerged” HPVs
  - Reached HPV level since Challenge launch
  - 2005 EPA data availability study on 235:
    - 52% had NO hazard data publicly available (compared to 43% in 1<sup>st</sup> HPV study)
    - 2% of them had complete screening data set publicly available (compared to 7% in 1<sup>st</sup> study)
  - Only 232 have been sponsored through industry’s unilateral Extended HPV Program



## Sources of data being submitted under the HPV Challenge



Lots of additional existing data being unearthed

High use of categories, SARs

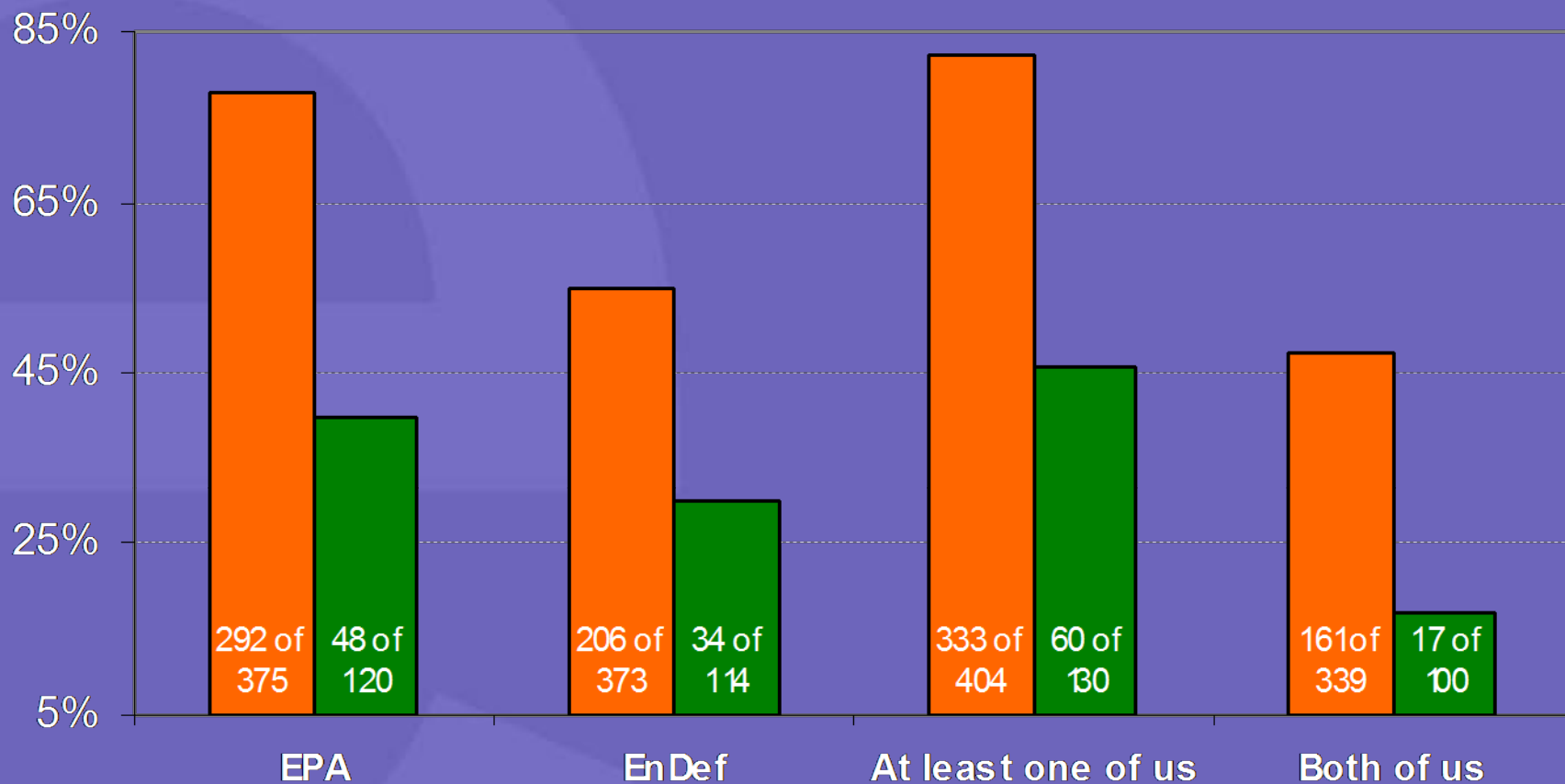
Contrary to initial concerns, limited use of laboratory animals and much less expensive than industry's initial estimates

## *Quality of Initial Industry Submissions Mixed*

CAVEAT – Prior charts are for *proposals*; EPA or Environmental Defense comments call for more testing or narrower categories in many cases:

- For 83% of test plans, EPA and/or ED indicate need for the sponsor to conduct additional data development or testing beyond that initially proposed.
- For about half of proposed *category* test plans, EPA and/or ED indicate deficiencies in the definition of or justification for the proposed category.
  - Categories account for 1/3 of test plans but 80% of Challenge chemicals

# Summary of Test Plan Comments



■ More testing needed/insufficient information
 ■ Disagreed with category justification

*Values shown are: test plans receiving a given comment / total test plans reviewed*

# Test Plan “Fatigue”?

**HPV Test Plan Grade Point Average, by Year**  
*Grades assigned by Environmental Defense*



## *HPV Program “Fatigue”?*

- EPA has fallen behind in reviewing test plans
  - No EPA comments yet on 20 of last 35 test plans with comments past due (up to 18 months late)
- Industry responses to EPA comments show increasing resistance to do more testing or revise categories

## *Public Access to Program Information*

U.S. HPV Challenge Program is part of EPA's Chemical Right-to-Know Initiative, yet:

- Industry failed to provide comprehensive tracking system it promised (same for EHPV?)
- EPA repository database for final sets of HPV chemical hazard data:
  - launch was years late
  - still being populated (now up to 850 chems)
  - still limited functionality



## Public Access to Program Information (cont.)

Environmental Defense developed and maintains the online  
**HPV Tracker** [www.environmentaldefense.org/go/hpvtracker](http://www.environmentaldefense.org/go/hpvtracker)

### HPV TRACKER -- © 2006 Environmental Defense

The current version reflects all information made public by EPA via its HPV Challenge Program web site, as follows:

- The EPA summary table of program commitments, dated **1-20-06**, and available at [www.epa.gov/chemrtk/pubs/sumresp.htm](http://www.epa.gov/chemrtk/pubs/sumresp.htm).
- All test plans, comments on test plans and revised test plans posted on the EPA website through **11-30-06**, and available at [www.epa.gov/chemrtk/pubs/summaries/viewsrch.htm](http://www.epa.gov/chemrtk/pubs/summaries/viewsrch.htm).
- The designations of OECD status in Columns J, U and V are current as of **11-21-06**, based on the OECD's HPV Database, available at [es3-hq.oecd.org/scripts/hpv/](http://es3-hq.oecd.org/scripts/hpv/).
- The designations of orphan chemicals in Column D are current as of **11-30-06**, based on EPA's listing available at [www.epa.gov/chemrtk/index.htm](http://www.epa.gov/chemrtk/index.htm) (bottom of page).

Records shown in red have company/consortia/EPA comments or clarifications -- see Column W.

Restore default view      Remove all filters

Sort by CAS      Sort by Sponsor

If sponsored:

Is the chemical:  
 - sponsored (Sp),  
 - exempted (E1-3-5),  
 - being handled under OECD,  
 - unsponsored orphan (U/O), or  
 - unsponsored not orphan (U/not O)?

CAS Number	Chemical name	List origin	Is the chemical: - sponsored (Sp), - exempted (E1-3-5), - being handled under OECD, - unsponsored orphan (U/O), or - unsponsored not orphan (U/not O)?	Name of consortium with which commitment is associated	Sponsorship status	Committing company or consortium sponsor (a * denotes a consortium)	Start year currently listed for initiation of data development
50000	Formaldehyde	1990	Sp		I	*ICCA HPV Chemical Initiative	2000
50000	Formaldehyde	1990	Sp		I	BASF AG	
50000	Formaldehyde	1990	Sp	In unnamed consortium of US, European, and Japanese Companies	I	Borden Chemical, Inc.	
50000	formaldehyde	1990	Sp	In unnamed consortium:	I	Celanese Ltd.	2002
50000	formaldehyde	1990	Sp	In Formaldehyde Epidemiology, Toxicology, and Environmental Group	I	E.I. du Pont de Nemours and Company	
50215	Lactic acid	1990	Sp		F	PURAC America, Inc.	2002
50704	Glucitol, D-	1990	E1		NA	(none)	NA
50817	L-Ascorbic acid	1990	OECD		NA	(none)	NA
50997	D-Glucose	1990	E1		NA	(none)	NA
51285	Phenol, 2,4-dinitro-	1990	OECD		NA	(none)	NA
51661	p-Acetanisidide	1990	U/not O		NA	(none)	NA
54217	Sodium salicylate	1990	E5		NA	(none)	NA
55630	Nitroglycerin	1990	Sp		V	*U.S. Nitroglycerin Producers Consortium (USNPC)	2002
55630	Nitroglycerin	1990	Sp	In U.S. Nitroglycerin Producers Consortium (USNPC):	V	Alliant Techsystems Inc.	2002

## *Some Pluses of HPV Challenge*

- Full public access (database slow in coming)
- Public review opportunity
- Uses well-established test guidelines, reliability measures (EPA data quality review still to come)
- EPA (not industry) to assess hazard, risk
- Addresses large majority of chemicals by tonnage (>95%)
- Screening data being developed at much faster rate than prior efforts

## *Some Minuses of HPV Challenge*

- Screening-level data only: short on chronic endpoints, emerging concerns
- Hazard data focus; spotty, unverified use/exposure info
- Little recourse if quality is poor
- Reg. “backstop” weak: TSCA test rules
- “Old” toxicology: SIDS 20+ years old
- Excludes many 10,000s of nonHPVs, many of which will likely become HPVs

## *Some Lessons*

- Heavy reliance on unpublished data, estimates based on categories, QSARs
  - Clear guidance and extensive review, oversight crucial
- Test plan review is essential
- Response to comments should be required
- Public involvement adds value, transparency
- Accountability/tracking mechanisms essential
- Registry database must be established early

## *Success? Jury is still out*

- Challenge is limping a bit to the finish line
- Data quality and completeness a big unknown
- How will data be assessed and used?
- EPA resources insufficient, declining
- Industry is resisting making hazard data development and access “evergreen” practices



## *Industry's deceptive "spin" not helpful*

*"There never was any 'toxic ignorance.'"*

*"The chemical data gap has been closed."*

- Only 1/3 of needed data previously unpublished; quality often questioned
- Categories assembled, QSARs applied *in response to* program, not prior to it
- HPV Challenge still incomplete: overdue test plans/datasets, OECD chems, orphans, etc.
- EPA / ED called for more testing than proposed
- Data quality / completeness yet to be judged



## *Industry's deceptive "spin" not helpful*

*"There never was any 'toxic ignorance.'"*

*"The chemical data gap has been closed."*

- Emerging HPVs: big data gaps, paltry sponsorship, lacks accountability/transparency
- NonHPVs need data too; may be tomorrow's HPVs
- Implication that all HPV chemicals are also "safe" is unwarranted – many found to have hazardous characteristics
- Can't have it both ways: Claim extensive data exist even while exaggerating costs of REACH compliance by assuming no data exist!